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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/423,259

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97- MA- CNR-VI

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7590

12/21/2001

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EXAMINER

EINSMANN, JULIET CAROLINE

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 12/21/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,259

Applicant(s)

HANNI ET AL.

Examiner

Juliet C Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19, 21-23 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is written in response applicant's correspondence submitted 10/17/01, paper number 19. Claims 24 has been canceled and claims 19 and 22 have been amended. Claims 17-23 and 25-27 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/17/01 has been entered.

Claim Objections

3. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

4. Claims 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 22 is indefinite over the recitation “each primer being selected from” because with this recitation it is not clear if the primer pairs can be comprised of any two primers that are listed next, or if the claimed primer pairs are the specific groupings recited in the claims. Amendment of the claim to read “each primer pair being selected from” will obviate this rejection.

Claim Rejections - 35 USC § 103

5. Claims 17-19, 21-23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loftus *et al.* (PNAS USA, Vol. 91, pp. 2757-2761, March 1994) in view of Fei *et al.* (Animal Science and Technology (1996) Vol. 67, No. 10, pp. 900-905).

Loftus *et al.* teach the sequences of the D loops of the mtDNA from a number of cattle breeds. These sequences are fully disclosed in GenBank accession numbers L27712-27737. Instant SEQ ID NO: 2 consists of the complement of nucleotides 685-699 of the sequence disclosed in GenBank Accession number L27725 (see attached GenBank record). Instant SEQ ID NO: 5 consists of nucleotides 230-244 of the sequence disclosed in GenBank Accession number L27725.

Furthermore, the sequence taught by Loftus *et al.* and fully disclosed in GenBank accession number L27725 also comprises instant SEQ ID NO: 9-14. Instant SEQ ID NO: 9 consists of nucleotides 19-43, instant SEQ ID NO: 10 consists of the complement of nucleotides 158-177, instant SEQ ID NO: 11 consists of the complement of nucleotides 358-377, instant SEQ ID NO: 12 consists of nucleotides 441-60, instant SEQ ID NO: 13 consists of nucleotides 715-734, and instant SEQ ID NO: 14 consists of the complement of nucleotides 854-873.

Instant SEQ ID NO: 8 consists of nucleotides 225-705 of the sequence disclosed in GenBank Accession number L27725. Therefore, this sequence taught by Loftus *et al.* also comprises instant SEQ ID NO: 7 (nucleotides 310-336) and 19 (nucleotides 423-447), which are merely segments of SEQ ID NO: 8.

Instant SEQ ID NO: 15 consists of nucleotides 15824-15981 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 16 consists of nucleotides 225-337 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 17 consists of nucleotides 441-705 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 18 consists of nucleotides 745-902 of the sequence disclosed in GenBank Accession number L27712 (see attached GenBank record).

Loftus *et al.* do not teach nucleic acids which consist of the instantly claimed nucleic acids, nor do they teach primer pairs which comprise oligonucleotides that consist of the instantly disclosed sequences.

Fei *et al.* teach methods for specific identification of meat from cattle using the PCR with primers designed to amplify portions of the mitochondrial D-loop DNA sequence (p. 900-905). Primer BF taught by Fei *et al.* consists of nucleotides 397-416 of the sequence taught by Loftus *et al.* The primer taught by Fei *et al.* is considered to be a functional homologue of all of the primers and probes of the instantly claimed invention, since the primer disclosed by Fei *et al.* possesses the same function as those of the instant invention, namely to amplify and/or detect portions of the D loop mtDNA from cattle.

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In light of the sequences taught by Loftus *et al.* and the teaching by Fei *et al.* that beef samples can be specifically identified by PCR amplification of the D-loop of mitochondrial DNA, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have selected any primers from the sequences taught by Loftus *et al.* in order to have provided functional homologues of the primers taught by Fei *et al.* The selection of different primer pairs from the sequences taught by Loftus *et al.* would have provided the ordinary practitioner with additional mechanisms for the specific amplification and detection of D-loop mitochondrial DNA from beef products in meat samples. The ordinary practitioner would have had a more than reasonable expectation of success since Fei *et al.* teach that amplification with primers specific for the D-loop mtDNA of cattle results in the ability to detect small amounts of beef in a mixed meat sample, for example 0.1% of beef in pork.

Response to Remarks

Applicant's response noted that unexpected results presented in the form of a declaration may be helpful to overcome this obviousness type rejection, and Applicant indicated that such a declaration would be submitted as a supplement to the response filed 10/17/01. As of the time of the writing of this office action, no such response has been filed. Applicant is reminded that with regard to unexpected results, arguments of counsel are not found to be persuasive in the absence of a factual showing. MPEP 716.01(c) makes clear that

"The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant."

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The declaration will be considered when it is received. At this time, however, the rejection over Loftus *et al.* in view of Fei *et al.* is maintained for the reasons of record.

Allowable Subject Matter

6. The following is a statement of allowable subject matter as well as reasons for the indication of allowable subject matter: Claims which require the presence of nucleic acids consisting of SEQ ID NO: 3 or consisting of SEQ ID NO: 6 are unobvious over the prior art. While the prior art provides longer sequences which comprise SEQ ID NO: 3 and SEQ ID NO: 6, and the prior art provides motivation to design primers for the amplification of bovine mtDNA, this teaching is not sufficient to obviate nucleic acids which consist of SEQ ID NO: 3 or SEQ ID NO: 6. These nucleic acids are considered to be unobvious in light of the unexpected results provided in the specification, wherein these nucleic acids are shown to amplify bovine mtDNA but not that of horse, sheep, pig, duck, chicken or turkey (Figure 1). Further, nucleic acids consisting of SEQ ID NO: 3 and SEQ ID NO: 6 are shown to amplify mtDNA from many different breeds (Figure 2).

7. Nucleic acids consisting of SEQ ID NO: 1 and SEQ ID NO: 4 are also unobvious over the prior art of record because these nucleic acids comprise SEQ ID NO: 3 and SEQ ID NO: 6. It is assumed that, although slightly longer, these nucleic acids would function as primers with the same level of specificity as SEQ ID NO: 3 and SEQ ID NO: 6.

Conclusion


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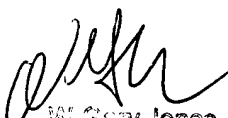
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Enclosed with this action, for applicant's convenience is a copy of the English language translation of the entirety of the Fei *et al.* reference.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Juliet C. Einsmann
Examiner
Art Unit 1655


W. Gary Jones
Senior Patent Examiner
Technology Center 1200

December 17, 2001